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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,748	10/27/2005	Alejandro Merino	085449-0159	6988

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EXAMINER	
LEE, JAE W	

ART UNIT	PAPER NUMBER
1656	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/521,748	MERINO ET AL.	
	Examiner	Art Unit	
	Jae W. Lee, Ph.D.	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *49-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *49-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *07/05/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Application status

In response to the previous Office action, a non-Final rejection (mailed on 02/27/2007), Applicants filed a response and amendment received on 07/27/2007. Said amendment canceled Claim(s) 1-48, 55 and 56, and amended Claim(s) 49-51 and 53. Thus, Claim(s) 49-54 is/are at issue and present for examination.

Applicants' arguments filed on 07/27/2007, have been fully considered, and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

The text of those sections of Title 35 U.S. Code not included in the instant action can be found in a prior Office action.

Objections to the Oath or Declaration

The Examiner acknowledges that Applicants are currently in the process of preparing a supplemental declaration to be submitted.

Claim Objections

The previous objection of Claim 49 (50-54 dependent therefrom) is withdrawn by virtue of Applicants' amendment, wherein they have amended Claim 49 as an independent claim.

The previous objection of Claim 49 (50-54 dependent therefrom) is withdrawn by virtue of Applicant's amendment, wherein they have deleted the recitations of non-elected inventions.

Claim 49 is objected to because the recitation of "KDA" can be improved with respect to clarity. The Examiner suggests replacing said recitation with ---kDa---.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 49-54 are rejected under 35 U.S.C. § 112, first paragraph, written description, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejection was stated in the previous office action as it applied to previous claims 49-54. In response to this rejection, Applicants have amended claims 49-53, and traversed the rejection as it applies to the newly amended claims.

Applicants argue that Applicants claims as amended do not recite "derivative," "fragment," or "variant,' and therefore the claims satisfy the written description requirement. Applicants also argue that a function, i.e., playing a biological role in beta-

amyloid precursor protein processing pathway, is associated with the proteins used in the complex of the claimed method, and therefore Applicants allege that this is adequate written description. Further, Applicants point out that claims are directed to a method of screening, and that such methods are well known to one of skill in the art, therefore Applicants allege that it is unnecessary to provide a working example of each and every single known method to produce a protein to provide adequate written description for the claims.

Applicants' arguments have been fully considered but are not deemed persuasive for the following reasons. The reason is that claims as amended are drawn to a method for screening for a molecule that binds to *a genus of protein complexes* comprising: (a) "HDAC1" (SEQ ID NO: 10); and (b) "SWI/SNF COMPLEX KDA SUBUNIT" (SEQ ID NO: 15).

It is noted by the Examiner that the recitations of SEQ ID NOs inside the parenthesis are interpreted to be examples of proteins "HDAC1" and "SWI/SNF COMPLEX KDA SUBUNIT." Therefore, "HDAC1" and "SWI/SNF COMPLEX KDA SUBUNIT" are interpreted as not being limited to the amino acid sequence as set forth in SEQ ID NOs 10 and 15, respectively.

As such, the claimed methods encompass methods of using a genus of protein complexes comprising "HDAC1" and "SWI/SNF COMPLEX 60 KDA SUBUNIT" or any fragment thereof. However, in this case, the specification fails to describe any identification of structural characteristics or properties of any protein complex comprising "HDAC1" and "SWI/SNF COMPLEX 60 KDA SUBUNIT" or any fragment

thereof that can be used by the claimed screening methods. Taken together, the genus of "protein complexes" encompasses widely variant species, having essentially any structure. Please refer to the M.P.E.P. section 2163 [R-5] under II, A, 3, (a), (ii) for more details with respect to sufficient number of representative species that should be disclosed to describe a widely variant genus. Therefore, the previous rejection under this statute is maintained for the reasons explained in the previous office action and herein.

Claims 49-54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, because the specification, while being enabling for a method for screening for a molecule that binds to a protein complex comprising SEQ ID NO: 10 and SEQ ID NO: 15, said method comprising the steps of: (a) exposing the complex or a cell or organism expressing the complex comprising SEQ ID NO: 10 and SEQ ID NO: 15 to one or more candidate molecules; (b) determining whether the one or more candidate molecules is are bound to the complex comprising SEQ ID NO: 10 and SEQ ID NO: 15; and (c) determining whether beta-amyloid precursor protein processing of the substrate is modified in the presence of the candidate molecule, does not reasonably provide enablement for a method of screening for a molecule that binds any protein complex comprising: (a) "HDAC1" (SEQ ID NO: 10); and (b) "SWI/SNF COMPLEX 60 KDA SUBUNIT" (SEQ ID NO: 15). Therefore, the specification does not enable any person skilled in the art to which it pertains, or with

which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The rejection was stated in the previous office action as it applied to previous claims 49-54. In response to this rejection, Applicants have amended claims 49-53, and traversed the rejection as it applies to the newly amended claims.

Applicants argue that the amended claims specifically require the screening method to be directed at a protein complex comprising HDAC 1 and SWI/SNF complex 60 kDa subunit proteins, which are disclosed as comprising SEQ ID NOs.: 10 and 15, respectively, and all language directed towards a "derivative," "fragment," or "variant" of the proteins have been removed. Further, Applicants point out that paragraphs [0543] to [0557], describe different types of assays and screening techniques that apply to the claimed invention, and that the disclosed methods are known to one having ordinary skill in the art.

Applicants' arguments have been fully considered but are not deemed persuasive for the following reasons. The reason is that the claims rejected under this section of U.S.C. 112, first paragraph, do not place any structural limits on the "protein complex," which are used in the claimed methods. It is noted by the Examiner that the "protein complex" is interpreted to encompass a protein complex comprising (a) "HDAC1" (SEQ ID NO: 10); and (b) "SWI/SNF COMPLEX 60 KDA SUBUNIT" (SEQ ID NO: 15) or any fragment thereof. With regard to the use of all "protein complexes" in the claimed method, it is noted by the Examiner that not all structurally different protein complexes would be able to play a role in beta-amyloid precursor protein processing

pathway. For this reason, a method of screening compounds that against any "protein complex" comprising any portion of (a) "HDAC1" (SEQ ID NO: 10); and (b) "SWI/SNF COMPLEX 60 KDA SUBUNIT" (SEQ ID NO: 15) would not enable one of skill in the art to identify compounds that modulate the beta-amyloid precursor protein processing so that they may be therapeutically beneficial for patients suffering from the Alzheimer's disease. Therefore, the claimed methods of using any protein complex comprising any portion of (a) "HDAC1" (SEQ ID NO: 10); and (b) "SWI/SNF COMPLEX 60 KDA SUBUNIT" (SEQ ID NO: 15) does not commensurate with the disclosure of the instant application. For the reasons described in the previous office action and herein, the rejection under this statute is maintained.

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 49-54 are rejected under 35 U.S.C. § 102(b) as being anticipated by Underhill et al. (A Novel Nuclear Receptor Corepressor Complex, N-CoR, Contains Components of the Mammalian SWI/SNF Complex and the Corepressor KAP-1, J. Biol. Chem., Vol. 275, Issue 51, 40463-40470, December 22, 2000).

The rejection was stated in the previous office action as it applied to previous claims 49-54. In response to this rejection, Applicants have amended claims 49-53, and traversed the rejection as it applies to the newly amended claims.

Applicants argue that the reference of Underhill et al. fails to teach the specifically claimed protein complex comprising both the HDAC1 and SWI/SNF complex 60 kDa subunit proteins in one protein complex. of the screening method, Applicants respectfully disagree. Also, Applicants acknowledges that claim 50 recites language that suggests an intended use of the method, however, Applicants allege that the claim actually limits the claimed molecule, by requiring a molecule that "modulates" the complex. Likewise, Applicants allege that Claims 52 and 53 have similar language to claim 50 in such a way that for claim 52, the language requires the molecule of claim 49 to be a drug that can treat or prevent a disease or disorder, and for claim 53, the language requires the molecule to "modulate the apoptotic activity" of the complex in claim 49.

Applicants' arguments have been fully considered but are not deemed persuasive for the following reasons. It is noted by the Examiner that the recitations of SEQ ID NOs inside the parenthesis are interpreted to be examples of proteins "HDAC1" and "SWI/SNF COMPLEX KDA SUBUNIT." Therefore, "HDAC1" and "SWI/SNF COMPLEX KDA SUBUNIT" are interpreted as not being limited to the amino acid sequence as set forth in SEQ ID NOs 10 and 15, respectively. Further, it is noted by the Examiner that "HDAC1" and "SWI/SNF COMPLEX KDA SUBUNIT" are not defined in the specification. Therefore, the claimed methods are interpreted to encompass the

use of any protein complex comprising (a) "HDAC1" (SEQ ID NO: 10); and (b) "SWI/SNF COMPLEX 60 KDA SUBUNIT" (SEQ ID NO: 15) or any fragment thereof. Therefore, the teachings of Underhill still anticipate the claimed methods.

With respect to the recitations of "intended use" in claims 50, 52 and 53, Applicants' arguments are not deemed persuasive because Applicants are claiming "methods," not "products." As such, Applicants assertion that those recitations further limit "the claimed molecule" is irrelevant. When the recitations of "intended use" does not affect or limit the active steps of the claimed methods, such recitations have little or no patentable weight. For the reasons described in the previous office action and herein, the rejection under this statute is maintained.

Conclusion

Claims 49-54 are rejected for the reasons as stated above. Applicants must respond to the objections/rejections in this Office action to be fully responsive in prosecution.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jae W. Lee whose telephone number is 571-272-9949. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen K. Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patent Examiner: Jae W. Lee, Ph.D.

RICHARD HUTSON, PH.D.
PRIMARY EXAMINER